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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	23

DATE MAILED: 06/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/362485	Flohe
Examiner	**Group Art Unit**
D. Johannsen	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/12/02.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Detailed Action

Office Action Summary

FINAL ACTION

1. This action is in response to paper no. 22, filed March 5, 2002. Claim 1 is now under consideration. Claims 2-8 and 10-18 have been withdrawn. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. Claims 2-8 and 10-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

4. It is noted that the restriction requirement was deemed proper and made final in the Office action of paper no. 11.

Claim Rejections - 35 USC § 112

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons stated below and in the Office action of paper no. 20.

The response traverses the rejection on the grounds set forth below. Applicants' arguments have been thoroughly considered but are not persuasive for the reasons given below.

First, the response argues that the specification at pages 31-33 discloses that some mycobacteria lacking AlaDH activity may be virulent, and states that "Thus, in order to determine the virulence of a mycobacterium, one of skill in the art must determine both the AlaDH enzyme activity and determine whether AlaDH DNA is present in the mycobacterium." This argument has been thoroughly considered but is not persuasive. While the specification does disclose that the "deletion of base 272" discussed on page 31 and referred to in the response correlates with the absence of AlaDH activity, the specification does not indicate that detection of this deletion allows one to determine whether a strain is virulent or avirulent, as suggested by Applicants' response. Rather, the specification merely indicates that slow growing mycobacteria having AlaDH activity are virulent, and that other strains lacking AlaDH activity may also be virulent (specification p. 33). The specification does not indicate that "to determine the virulence of a mycobacterium, one of skill in the art must determine both the AlaDH enzyme activity and determine whether AlaDH DNA is present," as stated in the response. In contrast (and as cited by the response), the specification clearly states at page 33 that "a slow-growing mycobacterium having positive AlaDH activity is virulent," indicating that the presence of AlaDH activity in a slow growing strain is alone indicative of virulence. Further, with respect to strains lacking AlaDH activity, the specification does not in fact indicate that detection of the sequence or structure of the gene

encoding AlaDH in strains lacking AlaDH activity may allow one to determine whether a strain is virulent or avirulent. Additionally, it is noted that the instant rejection arises from the absence of a disclosure of kits comprising the components of claim 1; the teachings at pages 31-33 do not disclose or otherwise provide basis for such a kit. Thus, applicants' arguments are not persuasive.

The response further argues that "the application as filed recites that '[t]he disclosure also includes all conceivable combinations of the individual features disclosed,'" referring to page 37, lines 6-7 of the specification. In response, it is again noted that (as discussed in, e.g., the Advisory Action of paper no. 17) even if this general statement regarding "all conceivable combinations" were sufficient to provide basis for the combination of two particular compositions or products not actually disclosed in combination with one another in the specification, the specification in the instant case does not in fact disclose a kit comprising nucleic acids which might form a "combination" with the disclosed enzymatic test kit. Accordingly, the present claim does not constitute a "conceivable combination" of the features of the invention, as nucleic acids present in a kit, container, etc., were never disclosed.

The response also urges that original claim 14 provides basis for the invention of present claim 1. However, as discussed in paper no. 17, claim 14 merely provides a further limitation of the type of sample to be "used" in different methods; the claim does not disclose that the two different methods may be combined, but merely indicates that the same type of sample may be employed in the two separate methods. Further, there is no disclosure in the specification of a single method in which all of the steps of these

two methods are carried out or in which all of the reagents of the product of claim 1 are employed, etc. While the response asserts that "the application as filed most certainly disclosed a method in which the claimed combination of components is employed," the response does not cite any actual instance of this teaching in the specification. Accordingly, this argument is not persuasive.

Finally, with respect to applicants' argument regarding an intended use recited in a claim preamble (citing *Rowe v. Dror*), it is noted that while the recitation "for the diagnosis of tuberculosis and other mycobacterial infections" in claim 1 does constitute an intended use, the requirement for a "kit" is a structural limitation, in that the claimed product must be present in a structure that would be considered by one of ordinary skill in the art to constitute a kit (e.g., a container, an enclosure, within packing materials, etc.). The instant specification does not disclose a kit comprising nucleic acids as required by claim 1; accordingly, basis for such a structure is lacking, and applicants' arguments are not persuasive.

This rejection is maintained.

Claim Rejections - 35 USC § 103

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al in view of Ahern, for the reasons set forth below and in the Office action of paper no. 20.

It is first noted that the rejection set forth in paper no. 20 states that Andersen et al disclose "methods" – not a single method – "for characterizing L-alanine dehydrogenase in which all the components set forth in claim 1 are employed." The

response traverses the rejection on the following grounds. The response argues that "no motivation to select these particular methods from Andersen has been identified" and that "the examiner is impermissibly picking and choosing from the Andersen disclosure, using the applicants specification as a guide to impermissibly arrive at these hindsight reconstruction of the claimed subject matter," citing *In re Mills*. This argument has been thoroughly considered but is not persuasive. The instant claim is not drawn to a method, but rather to a kit comprising particular components, all of which are disclosed by Andersen et al. Further, the claim recites the open transitional language "comprising," and is therefore not limited to, e.g., a specific combination of components with which unexpected results were obtained (and exclusive of other components). As set forth at pages 4-5 of paper no. 20, one would have been motivated to have packaged "any or all of the reagents taught by Andersen et al into a kit" in order to "have provided the reagents needed to perform Andersen et al's methods to practitioners in a convenient format for the advantages of efficiency and cost-effectiveness," as taught by the Ahern reference. Accordingly, Applicants' arguments are not persuasive.

The response further argues that "Andersen did not disclose a nucleic acid consisting of one of the expressly provided partial sequences" of the claim. In response, it is noted that the claim merely requires a nucleic acid consisting of a sequence "hybridizable" with one of the particular sequences under the recited conditions. The nucleic acid of Andersen et al clearly meets this requirement. Further, with respect to applicants' argument that Andersen does not disclose the use of the reagents of the instant claim in a single method, it is again noted that the claim

necessitates no such requirement, as it is drawn to a kit comprising components, not to a method or, more particularly, to a single method employing each of those components. Thus, applicants' arguments are not persuasive.

As the combined references of Andersen et al and Ahern suggest all the limitations of present claim 1, this rejection is maintained.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al in view of Ahern, as applied to claim 1, above, and further in view of Innis et al, for the reasons set forth below and in the Office action of paper no. 20.

The response traverses the rejection for the same reasons discussed in paragraph 6, above. Accordingly, the response to those arguments applies equally herein. Further, with respect to applicants' argument that "Andersen did not disclose a nucleic acid consisting of one of the expressly provided partial sequences" of the claim, it is noted that the instant rejection did not make such an assertion. Rather, the Innis et al reference was cited for its guidance with respect to the preparation of primers for use in PCR (see p. 5-7 of paper no. 20). Additionally, it is again noted that the claim is not in fact limited to the particular sequence recited therein.

As the combined references of Andersen et al, Ahern, and Innis et al suggest all the limitations of present claim 1, this rejection is maintained.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
June 10, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600